

### REMARKS

These remarks respond to each rejection presented in the Office Action mailed August 24, 2005.

#### I. 35 U.S.C. §102

##### **A. Grollier et al. U.S. 4,767,618 ("Grollier")**

Grollier discloses a cosmetic composition for hair and skin treatment, which includes at least 5% pulverized plant particles (Abstract). At col. 4, lines 34-42, Grollier catalogs a large number of plants. It includes *Indigofera tinctoria* (or "indigo") amount the plants said to be

"capable of imparting a color to the compositions containing them or capable of **coloring the keratin of the hair or skin.**" [emphasis is added].

Claim 1 features,

A pharmaceutical composition comprising an effective amount of bioactive trans-tetracos-15-enoic acid **extracted** from a plant *Indigofera tinctoria*, used for the **treatment of subjects with hepatic disorders.** [emphasis is added].

The Examiner does not (and could not) take the position that Grollier discloses that trans-tetracos-15-enoic acid can be extracted from *Indigofera tinctoria*. Nor does or could the Examiner take the position that the use of *Indigofera tinctoria* to treat hepatic disorders. Rather, the Examiner concludes that Grollier (as well as the other cited references)

teach[es] that *Indigofera tinctoria* is known to be used in compositions, namely cosmetic types. Bioactive transtetracos-15-enoic acid is inherently in the plants since that is where the acid is extracted from.

In other words, the Examiner has ignored two components of claim 1 (highlighted above): the requirement for extraction and the requirement for use to treat hepatic disorders. The Examiner is not free to ignore a claim limitation. There is no basis to conclude that one skilled in the art following the teaching of Grollier would inherently **extract** *Indigofera tinctoria* to produce trans-tetracos-15-enoic acid and then use the extract to treat hepatic disorders. The standard for inherent anticipation is a strict one. See for example *Akamai Technologies, Inc. v. Cable &*

*Wireless Internet Services*, 344 F.3d 1186, 68 USPQ2d 1186 (Fed. Cir. 2003) which says the unexpressed claim limitation (in this case, e.g., extraction of trans-tetracos-15-enoic acid) must **necessarily** be present in the prior art, not merely probably or possibly present. The MPEP requires the Examiner to meet the same standard (MPEP 2112 (p. 2100-52)):

EXAMINER MUST PROVIDE RATIONALE OR EVIDENCE TENDING TO SHOW INHERENCY  
The fact that a certain result or characteristic may occur or be present in the prior art is not sufficient to establish the inherency of that result or characteristic. In re Rijckaert, 9 F.3d 1531, 1534, 28 USPQ2d 1955, 1957 (Fed. Cir. 1993) (reversed rejection because inherency was based on what would result due to optimization of conditions, not what was necessarily present in the prior art); In re Oelrich, 666 F.2d 578, 581-82, 212 USPQ 323, 326 (CCPA 1981). "To establish inherency, the extrinsic evidence 'must make clear that the missing descriptive matter is necessarily present in the thing described in the reference, and that it would be so recognized by persons of ordinary skill. Inherency, however, may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient.' " In re Robertson, 169 F.3d 743, 745, 49 USPQ2d 1949, 1950-51 (Fed. Cir. 1999) (citations omitted) ....  
"In relying upon the theory of inherency, **the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.**" Ex parte Levy, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990) (emphasis in original) ...

The Examiner is respectfully requested to withdraw this rejection or provide the requisite basis for a conclusion that extraction and treatment of hepatic conditions is **necessarily present** in the prior art.

Claim 1 as well as the dependent claims are patentable over Grollier, and the Applicants respectfully ask the Examiner to withdraw the rejection.

**B. Nguyen U.S. 5,897,865**

Nguyen is even further afield. It discloses treatment of medical disorders (skin conditions, gastrointestinal disturbances, pain and other troublesome medical disorders, by administering tumeric. See col. 1, lines 11-13. Nguyen goes on to say that the tumeric can be formulated (combined) with other herbs and plants "depending on the desired purpose and effect". Nguyen lists a large number of such herbs and plants, including *Indigofera tinctoria*. Here again there is no mention of extracting trans-tetracos-15-enoic acid from *Indigofera tinctoria* and no mention of treating hepatic disorders. The art provides no basis to conclude that it would be beneficial for treating hepatic disorders.

Applicants respectfully request that the rejection be withdrawn.

**C. WO 99/11223**

WO '223, like Grollier, concerns the use of indigo as a hair treatment. For the reasons given above, WO '223 does not anticipate the claims as amended.

Applicants respectfully request that the rejection be withdrawn in view of the amendment.

**D. JP 49019039 (English Abstract)**

The abstract of JP '039 discloses a skin protection composition that includes dehydrodholic acid. JP '039 (Abstract) does not have any teaching related to treating hepatic conditions.

Applicants respectfully request that the rejection be withdrawn.

**II. 35 U.S.C. §103**

For the reasons noted above, the claims specify treating hepatic conditions. Such treatment would not be obvious from the skin/hair treatments in the prior art (the references discussed above). The Examiner has failed to explain why the claim features that are missing from the prior art would be obvious or how they would inherently occur according to the theory of the obviousness rejection.

Applicants respectfully request that the rejection be withdrawn.

Applicant : Handa et al.  
Serial No. : 10/073,548  
Filed : February 11, 2002  
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Attorney's Docket No.: 07064-012001 / FP00820-  
NF236/99-VK

Enclosed is a \$450 check for the Petition for Extension of Time fee. Please apply any other charges or credits to deposit account 06-1050.

Respectfully submitted,

Date: \_\_\_\_\_

*Jan 24, 2006*

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